

REMARKS

Claims 34-37, 39, 41, 43, 44 and 71, as amended, remain herein.

Claim 71 has been amended to moot the §112, paragraph 2 rejection thereof, and now is fully in condition for allowance.

1. Claims 34-36, 39, 41, 43 and 44 were rejected under § 103(a) over Lyle '713 in view of Crocker '742. This is a restatement of the same issue raised in the December 23, 2005 Office Action, but no convincing rebuttal of applicants' traversing arguments is present in the Office Action of July 11, 2006.

Lyle '713 discloses a composition and method of therapeutic treatment for inhibiting vascular restenosis. Lyle, col. 4, lines 35-40 disclose administering in vivo an antisense polypeptide or oligonucleotide or molecule having similar specificity by using a balloon infusion catheter with holes in it for delivery to the particular target site to prevent life-threatening restenosis. However, this is the only description of a "balloon infusion catheter with holes in it" in Lyle '713. Lyle '713 does not disclose a substantially hollow seed for implantation into a tissue or organ, which seed has an opening at each end thereof for providing controlled diffusion of a therapeutic agent from such hollow seed. Nothing in Lyle '213 or in the Office Action shows such a seed.

Thus there is no disclosure or teaching in Lyle '713 of all elements of applicant's claimed invention, and there is no disclosure or teaching in Lyle '713 which would have suggested applicant's claimed invention to one of ordinary skill in the art.

Crocker '742 discloses a radiation delivery balloon for a balloon catheter that includes a central zone 32 and proximal zone 28. At an inflation pressure of about 8 atm., the proximal zone 28 has an outside diameter of about 3 mm and the central zone 32 has an outside diameter of about 3.4 mm. As shown in Figs. 3 and 4, a large zone 32 is provided with a radiation source 34 surrounded by outer sleeve 38. Alternatively, the outer sleeve 38 can be omitted, and radiation source 34 adequately secured to the exterior of the balloon.

However, Crocker, like Lyle, does not disclose hollow seeds for implantation into a tissue or organ, which seeds have an opening at each end thereof. The balloon catheters mentioned in both Lyle and Crocker are not seeds for implantation, and cannot be used as an implantable seed because it is necessary to have central guide wire running through both ends of such balloons and secure them to the catheter. The Office Action assumes that “such a wire would not preclude implantation,” but does not explain any factual basis in either of the cited references (or any other logic) for such a conclusion—which is completely naked and without foundation in this record.

Thus, there is nothing in either Lyle or Crocker which in any way suggests a hollow seed for implantation, let alone such a seed for implantation having an opening at each end thereof, to provide controlled diffusion of a therapeutic agent out of the hollow seed. And contrary to the unsupported conclusion in the Office Action, there is nothing in Lyle or Crocker that would make it obvious to use a balloon catheter as an implantation seed to be left in a live body. Nor is there any disclosure or teaching in either Lyle or Crocker that would have suggested the desirability of combining any portions thereof effectively to anticipate or suggest applicant's

presently-claimed invention. Accordingly, reconsideration and withdrawal of these grounds of rejection are respectfully requested.

2. Claims 34-47, 39, 41, 43 and 44 were rejected under § 112, second paragraph, the Office Action alleging that the recitation of "a nucleic acid sequence" in independent claim 34 is indefinite. This is the same issue raised in the Office Action of December 23, 2005, but no convincing rebuttal of applicants' traversing arguments is presented in the Office Action of July 11, 2006.

Applicant's specification, page 15, line 7-16, explains the phrase "nucleic acid sequence," saying that the claimed seed will comprise "a therapeutic nucleic acid sequence e.g., a radiation-sensitizing gene, antisense DNA, ribozyme, virus, plasmid, et seq." The July 11, 2006 Office Action does not deny that the term "nucleic acid sequence" is well-known. Even the Lyle '713 reference cited in the Office Action makes it clear that "it is not necessary that the entire oligonucleotide sequence be present." Lyle '713, col. 4, lines 31-32. The Office Action seems to imply that it would be necessary to recite a whole molecule for such a term to satisfy § 112, second paragraph. Lyle '713, as well as applicant's specification, and the notorious knowledge of those skilled in the relevant arts, all demonstrate that the Office Action is in error. The statement in the July 11, 2006 Office Action that "sequence" suggests some engineered polynucleotide of unspecified sequence rather than the natural polynucleotides disclosed" completely begs the question of whether applicant has claimed what he regards as his invention in terms understandable to one skilled in the relevant art. The term used by applicant is well understood by those skilled in the art. The speculation in the Office Action that the term "suggests"

something else is without merit and is neither probative nor persuasive. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

For all the foregoing reasons, all claims 34-37, 39, 41, 43, 44 and 71 are now patentably distinguished over all grounds of rejection cited in the Office Action. Accordingly, allowance of all claims is respectfully requested.

The PTO is hereby authorized to charge/credit any deficiency/overpayment to Deposit Account No. 19-4293 (Order No. 28964.0054). Should the Examiner believe that further changes would place this application in even better condition for issue, the Examiner is invited to telephone applicant's undersigned attorney.

Respectfully submitted,

STEPTOE & JOHNSON LLP



Roger W. Parkhurst
Registration No. 25, 177

January 11, 2007

RWP/tlpdg
Atty Dkt: 28964.0054

STEPTOE & JOHNSON LLP
1330 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 429-6420